PT. SINKO PRIMA ALLOY

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CONTENT

CONTENT 1

User Responsibility 2

Safety and Operating Precautions 2

1. INTRODUCTION 4

2 STRUCTURE AND WORKING PRINCIPLE 5

2.1 Structure 5

2.2 Working Principle 6

3 SPECIFICATION 6

4 INSTALLATION 6

5 PERFOMANCE CHECK 8

5.1 FiO_2 Check 8

5.2 Alarm Check 9

5.3 Reverse Flow Check 9

5.4 Gas Tithtness Check 10

6 CLEANING AND STERILIZATION 10

7 TROUBLESHOOTING 11

8 PNEUMATIC SCHEMATIC DIAGRAM 12

9 WARRANTY 12

User Responsibility

This product must be installed, operated, maintained and repaired in accordance with the instructions for use, the attached label, and the insert. This product must be inspected regularly and users should not use defective products. Parts that are damaged, lost, excessively worn, deformed or contaminated must be replaced immediately.

Safety and Operating Precautions

Please read this safety instruction carefully. This safety instruction is an integral part of the equipment and must be available at all times.

	Warning. If the warning is not heeded, it may cause death or serious injury.
	Caution. If the caution is not taken, it may cause minor or moderate injury.

Warnings!

- The equipment should be only installed, operated, maintained and repaired by the manufacturer, one of its representatives or a service provider authorized by the manufacturer.
- The air-oxygen blender can be only used for the intended

purpose.

- If either the air or oxygen gas source fails, the blender alarm sounds, alerting the clinician that a condition has been occurred that may significantly alter the FiO_2 and flow output.
- If the pressure difference of the gas sources exceeds 0.15 MPa (22 psi), the blender alarm sounds. In this condition, the FiO_2 and flow output of the device may alter significantly.
- DO NOT steam clean, autoclave the blender or subject the unit to temperatures above 62°C (145°F).
- DO NOT immerse the air-oxygen blender assembly in a liquid detergent.
- DO NOT block or remove the alarm whistle at any time.
- A qualified oxygen analyzer is recommended for monitoring gas output and inspecting the FiO_2 adjustment.

Cautions!

- To prevent respiratory damage, the respiratory system should only be connected to clean, dry, medical-grade gas sources. Contamination or moisture can cause undesirable operation.

- Air used for medical purposes should meet USP compressed air and/or ANSI Z86.1 1973 grade F, and water vapor content must not exceed a blender's dew point of 5°F below the lowest ambient temperature to which the delivery system is exposed.
- The blender shall not exceed 5.63 grams H_2O per cubic meter of non-condensable gas.
- When using an oxygen cylinder supporting the use of air-oxygen blender, it is recommended to use a pressure relief valve that is compatible with the wall gas supply fitting. If the gas in the cylinder is exhausted, the above method can ensure a closed transfer of the respiratory system and the wall gas source.
- Uninterrupted observation of the patient and oxygen concentration must be performed during ventilation.
- Relying on the respiratory system for too long might lead to patients' muscle atrophy.

1. INTRODUCTION

Elitech Medical Air-Oxygen Blender SPA02 is a compact, lightweight blender that provides precise mixing of medical air and

oxygen. The blender can be used with incubators, warmers, oxygen hoods, masks, resuscitators, etc.

2 STRUCTURE AND WORKING PRINCIPLE

2.1 Structure

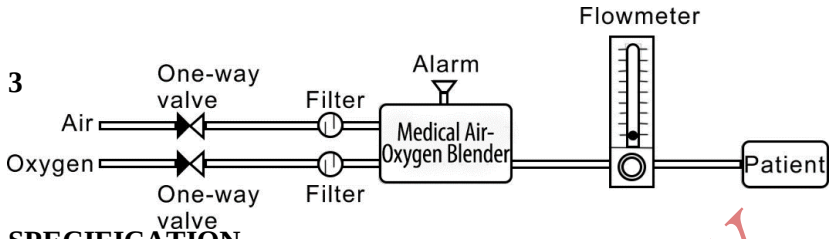
With control knobs on the front of the unit for oxygen concentration and flow rate adjustment, the blender allows selection of oxygen concentrations and flow rates. Oxygen concentrations ranging from 21% to 100% are available.

The blender is mainly comprised of three parts.

- Balance module
- Proportioning module
- Alarm

2.2 Working Principle

3

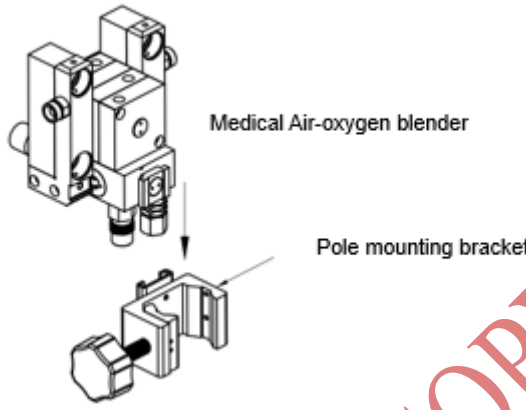


SPECIFICATION

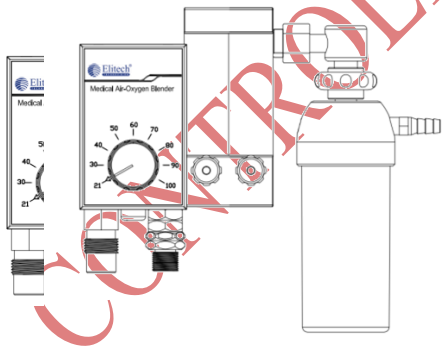
Model	SPA02	
FiO_2	21% ~ 100 %	
Flow	0.1-1 & 2-18 LPM	
Pressure	Air/Oxygen@0.3-0.4 MPa	
Alarm	Ketika tekanan suplai gas > 0.15 MPa	
Alarm Noise	>57 dB(A)	
Number of Output	Dual	
Accuracy of FiO_2	3%	
Bleed Flow	3 LPM	
Operating	Temperature	-18° ~ 50°C
	Humidity	≤ 95% RH
	Atmosphere Pressure	800 ~ 1060 hPa
Storage	Temperature	-40° ~ 60°C
	Humidity	5% ~ 95% RH
	Atmosphere Pressure	800 ~1060 hPa

4 INSTALLATION

1. Fix the pole mounting bracket on a pole near the patient.
2. Fix the air-oxygen blender vertically on the pole mounting bracket.



3. Connect the air/oxygen high pressure tubes (O_2: blue, Air: black) to the inlet ports.
4. Connect the outlet port to Humidifier bottle(ref.pic4.4.1) or proper connector (ref.pic 4.4.2).



Pic 4.4.2

5 PERFOMANCE CHECK

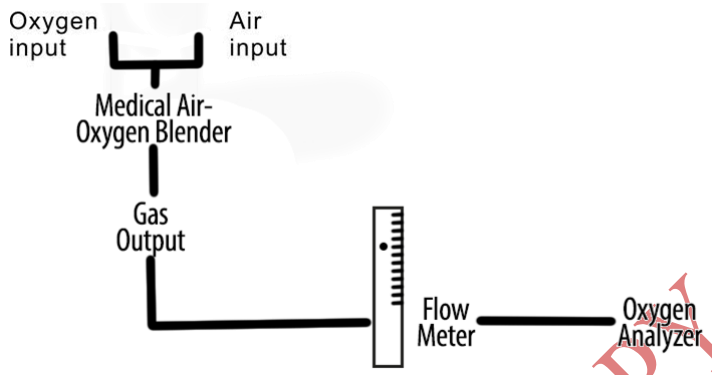
Warning!

The following performance checks should be conducted before clinical use. If the blender does not function as described below, please contact the manufacturer, one of its representatives or a service provider authorized by the manufacturer.

5.1 FiO_2 Check

A qualified oxygen analyzer is recommended for monitoring gas output and inspecting the FiO_2 adjustment.

1. Connect the air and oxygen gases to the inlets of the blender.
2. Connect the oxygen analyzer to the blender.
3. Adjust the flow rate to 5 L/min.
4. Adjust FiO_2 of blender to 21%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, and observe the FiO_2 reading on oxygen analyzer.
5. When it is found that the value shown on the oxygen analyzer is significantly different from the indicated value of FiO_2 adjustment knob (> ±5%), the blender needs to be calibrated.



5.2 Alarm Check

No	Adjustment	Alarm Response
1	Connect the 0.3-0.4 MPa (43.5-58 psi) air and oxygen gases to the inlets of blender. Adjust the flow rate at 2 L/min and FiO_2 at 60%.	The alarm should not activate.
2	Disconnect the air source.	Audible alarm activates.
3	Reconnect the air source.	Audible alarm stops.
4	Disconnect the oxygen source.	Audible alarm activates.
5	Reconnect the oxygen source.	Audible alarm stops.

5.3 Reverse Flow Check

Reverse flow is a measure of the amount of leakage under normal state or a single fault state. The reverse flow shall not exceed 10 ml/h under normal operating conditions or in a single fault condition without an alarm. The reverse flow should not exceed 100 ml/min under the single fault condition indicated by the alarm.

5.4 Gas Tithtness Check

Connect the 100 ml/min flow meter to the oxygen gas source input port, and then turn off the air-oxygen blender. The flow rate should be less than 50 ml/min. If the flow rate is above 50 ml/min, it indicates a leakage.

6 CLEANING AND STERILIZATION

- Before stop using the blender, it is recommended to cut off the gas sources, adjust the FiO_2 to 21%, and adjust the flow rate to the off state.
- The exterior of the blender should be wiped with a slightly damp cloth dampened with disinfectant to prevent liquid from entering the device.
- The accessories should be cleaned and disinfected within 24 hours to prevent the growth and reproduction of pathogenic microorganisms and cross infection. Wash them thoroughly with liquid cleaner, remove all traces, blood stains, oil stains and other residual dirt. After washing, soak disinfection for 30 minutes should be performed.
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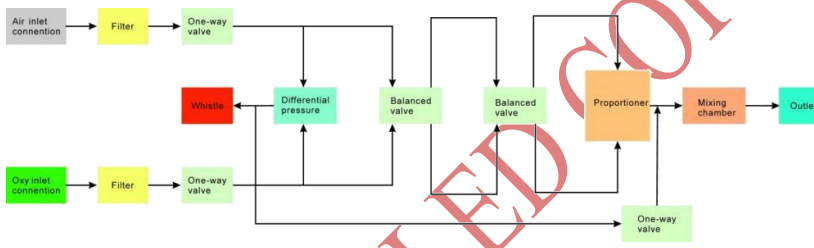
7 TROUBLESHOOTING

No	Problem	Potential Cause	Corrcetive Action
1	Alarm sounding	1 Oxygen source lacks pressure 2 Air source lacks pressure 3 Large pressure difference	1 Check oxygen source 2 Check air source 3 Check pressure
2	Low flow rate	1. Gas leakage 2. Improper parameters	1. Check connection 2. Adjust parameters 3. Contact manufacturer
3	No flow output	1. Gas source supply interruption	1. Check gas source 2. Adjust flow

		2. Flow rate unset	rate 3. Contact manufacturer
4	Inaccurate FiO_2	1. Significant pressure difference 2. Blender out of calibration	1. Check pressures 2. Contact manufacturer

8 PNEUMATIC SCHEMATIC DIAGRAM



FiO_2	Fractional Concentration of Inspired Oxygen
MPa	Megapascal
psi	Pound Per Square Inch
°C	Derajat Celcius
°F	Derajat Fahrenheit
LPM	Liter per menit

9 WARRANTY

Warranty Sinko Prima Alloy warrants that PT. SINKO PRIMA ALLOY's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period. The warranty is void in cases of:

A. Damage caused by mishandling during shipping.

B. Subsequent damage caused by improper use or maintenance.

C. Damage caused by alteration or repair by anyone not authorized by PT. SINKO PRIMA ALLOY.

D. Damage caused by accidents.

E. Replacement or removal of serial number label and manufacture label. If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, PT. SINKO PRIMA ALLOY will, at its discretion, repair or replace the defective part(s) free of charge. PT. SINKO PRIMA ALLOY will not provide a substitute product for use when the defective product is being repaired. Contact Information If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor. Alternatively, you can send an email to PT. SINKO PRIMA ALLOY service department at: aftersales@elitech.co.id.

MEDICAL AIR-OXYGEN BLENDER

SPA02

MANUAL BOOK

Elitech® TECHNOVISION